

K92494

APR 16 1997

## SUMMARY OF SAFETY AND EFFECTIVENESS

### CHASE CURVED LEFT HEART VENT CATHETER

#### I. General Information

- A. Generic Name: Curved Left Heart Vent Catheter
- B. Trade Name of Device: CHASE CURVED LEFT HEART VENT CATHETER
- C. Applicant's Name and Address: CHASE MEDICAL INC. , Richardson, TX
- D. Pre-market Notification Number: Not assigned

#### II. Indication for Use:

The CHASE Curved Left Heart Vent Catheter is indicated for use in venting the left heart during cardiopulmonary bypass with entrance made at the juncture of the right superior pulmonary vein with the left atrium and passing through the mitral valve.

#### III. Device Description

The vent catheter consists of a preformed, flexible plastic tube, (20 French), with a perforated section. A small tapered tip of rigid plastic is attached to the perforated section to aid in the insertion of the catheter. A rigid plastic tube connector for 6.4mm (1/4") I.D. tubing is permanently attached to the other end of the catheter tube. Marking rings on the tube serve as an indication of insertion depth.

#### IV. Device Classification: Class II device

#### V. Safety and Effectiveness:

Substantial Equivalence: This device is substantially equivalent to the Sarns Curved Left Heart Vent Catheter K770430.

#### VI. Other Safety and Effectiveness Data:

- Materials: All material are identical to the predicate device.
- Sterilization: Validated 100% Ethylene Oxide sterilization cycle (Overkill Method) SAL  $10^{-6}$

#### Functional Testing

All functional characteristics of the Chase Medical Curved Left Heart Vent Catheter are non-differentiable as compared with the predicate because both devices have the exact same fit, form, and material composition.

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<b>Leak Test Requirements:</b>	<b>No leaks at 10 psi air on Chase device at 4°C and 40°C</b>
<b>Tubing Bond Strength:</b>	<b>Exceeds 10 lb. tensile strength @ 4°C and 40°C</b>
<b>Package Integrity:</b>	<b>Tyvek/Polymylar passed burst test per ASTM F1140-88</b>
<b>Shipping &amp; Distribution Testing:</b>	<b>Per National Safe Transit Ass. vibration and drop tests</b>
<b>Accelerated Aging:</b>	<b>Two year shelf life</b>